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<p>(21) International Application Number: PCT/US95/07576 (22) International Filing Date: 14 June 1995 (14.06.95) (30) Priority Data: 08/259,663 14 June 1994 (14.06.94) US (71) Applicant: SCIMED LIFE SYSTEMS, INC. [US/US]; One Scimed Place, Maple Grove, MN 55311-1566 (US). (72) Inventor: LA FONTAINE, Daniel, Marc; 11400 Fifth Avenue North, Plymouth, MN 55441 (US). (74) Agents: BRUESS, Steven, C. et al.; Merchant, Gould, Smith, Edell, Welter & Schmidt, 3100 Norwest Center, 90 South Seventh Street, Minneapolis, MN 55402 (US).</p>		<p>(81) Designated States: CA, JP, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>
<p>(54) Title: ELECTROPHYSIOLOGY DEVICE</p> <div data-bbox="357 1102 1291 1417"></div> <p>(57) Abstract</p> <p>An ablation and mapping catheter is disclosed which incorporates a fluid electrode for contacting tissue. The fluid emerges along the length of the catheter to generate a linear lesion in the cardiac tissue.</p>		

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ELECTROPHYSIOLOGY DEVICE

Cross Reference to Related Applications

The present application is a continuation-in-part of U.S. Patent Application entitled "Electrophysiology Energy Treatment Devices and Methods of Use", filed November 13, 1992, and having serial number 07/976,406. This parent application is incorporated by reference in its entirety.

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1. Field of the Invention

The present invention related to electrophysiology and more particularly to a device and method of operation for an ablation instrument.

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2. Background Art

Arrhythmias can be treated in a number of ways. The traditional treatment has been the systemic administration of anti-arrhythmia drugs. However there is a narrow difference between a therapeutic dose and a toxic dose of the most effective drugs. In many instances the drugs induce bradycardia and the patient may receive a heart pacemaker to treat this induced condition.

Another approach is to treat the arrhythmia with electrical stimulation of the ventricle to interrupt the arrhythmia and convert the heart to normal sinus rhythm. This process may be performed with an implanted device.

A third approach is ablation. Many arrhythmias result from accessory electrical pathways which participate in the generation and continuation of tachy-arrhythmias. It is possible to destroy these accessory pathways by selectively ablating the offending tissue. The application of heat or other energy disrupts and injures the tissue and slows down or prevents the conduction of electrical impulses. The principle benefits of ablation therapies flow from the fact that no implantable device is required nor is a

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prolonged and expensive drug therapy required. Thus the patient experiences an improved quality of life at a reduced overall cost.

The principal problems related to ablation stem from the requirement to localize the conduction disturbances and then to deliver the ablation energy to the same selected conduction site. This is exceedingly difficult to do given the constant motion of the heart. The energy densities used for radio-frequency ablation are sufficient to "boil" the blood and cause tissue to adhere to the catheter tip. Therefore these therapies must be delivered with care. Therefore there exists a continuing need to improve the ability to deliver ablation energy to heart tissue.

SUMMARY

The present invention is a catheter system that can be used for contact mapping and for the delivery of radio-frequency energy along a segment of the catheter which forms a "linear" lesion in the tissue. The catheter relies on a fluid electrode to conduct the RF energy to the tissue. The fluid electrode is preferably a normal saline solution delivered from a pump or the like under the control of the physician. A porous dielectric surface helps to direct the fluid electrode into contact with the tissue.

BRIEF DESCRIPTION OF THE DRAWINGS

The various figures of the drawing set forth an illustrative and exemplary form of the invention. Throughout the various figures identical reference numerals refer to identical structures, wherein:

FIG. 1 is a view of the invention with the distal tip enlarged to clarify certain details of construction;

FIG. 2 is an enlarged view of the distal portion of the invention;

FIG. 3 is a view of an alternative embodiment of the invention.

DETAILED DESCRIPTION OF THE INVENTION

5 FIG. 1 shows the electrophysiology device 10 as part of system. The system includes an energy source 20, a fluid pump 28 coupled to a fluid source 24 through an appropriate tube 26. The fluid pump 24 draws fluid from the fluid source and forces fluid through the
10 central fluid lumen 40 of the catheter 32. A Y-shaped manifold 12 couples the energy source 20 and the fluid system to the catheter 32.

 The energy source 20 is coupled to the electrode 38 through a wire 22. This wire 22 passes
15 through a sheath 30 and terminates at a connection 50 located on an electrode 38. The RF energy exits the distal open end 52 of the catheter 32 and passes through the heart tissue 11 as indicated by arrow 13. RF current passing through the heart tissue 11 is collected
20 at the exterior of the patient through a patient pad 21 and is returned to the energy source 20 through return path wire 23 completing the electrical circuit. Experimental work has been performed with an energy source delivering approximately 50 Watts of power
25 delivered into 100 Ohms at about 500 KHz.

 The RF energy is confined and directed by a fluid flowing through the fluid lumen 40 of catheter 32 tube. In general, a reservoir or fluid source 24 is provided to store an electrolyte fluid shown in the
30 figure by arrow 54. In practice the electrolyte is a saline solution formed by the addition of 35 G of NaCl to 100 ml of water. This balanced saline works well but higher ionic concentrations may be more effective for some applications where the additional salinity is well
35 tolerated. A modest flow of electrolyte 52 is induced by pump 28 to direct fluid flow against the cardiac tissue 11. In use, the moving saline forms a fluid

electrode to assist in the delivery of energy to the tissue 11.

FIG. 2 shows a detail of the distal end of the catheter 32. The drawing shows that the fluid 54 receives the RF energy by passing over the interior of electrode 38. This electrode 38 is located a short distance from the open end 52 of the catheter 32. In general, it is desirable to have a short path length from the electrode 28 to the tissue 11. But it is also desirable to locate the electrode 38 a sufficient distance from the tissue 11 to prevent adhesions and the like from contaminating the surface of the electrode 38. The catheter shown in FIG. 2 is particularly effective in making relatively isolated lesions in part because the fluid exits the catheter "axially" at the very distal tip of the catheter 32 body.

FIG. 3 shows a catheter 16 that is adapted to generate a "linear" lesion 14 which extends along the length of the active zone 15 of the catheter 16. In this construction a number of electrodes typified by electrode 18 are aligned along the length of the catheter body 25. The electrodes are coupled to the energy source or other switching structures through wires typified by wire 37. The catheter body 25 has an axis 36. The central lumen 27 of the catheter body 25 is coupled to the fluid source 28 (not shown). The fluid as it moves into the active zone 15 connects to the energy source 20 (not shown) and exits from the catheter body 25 "radially" by migrating through several holes typified by hole 29. A porous sheath 34 overlays the hole pattern and helps to regulate the passage of fluid from the lumen 27. The porous sheath 34 places a porous surface proximate the tissue 11. The multiple electrode sites permit the catheter to be quite flexible over the length of the distal segment. If each electrode set is independently accessible through separate connections for mapping studies then the

catheter 16 may be used for mapping when the central lumen 27 is filled with a dielectric fluid. Once the ectopic site has been located the central lumen may be quickly filled with the non-dielectric, electrolyte saline solution to perform ablation. In general, the presence of saline in the lumen will partially "short" out the electrodes and during ablation the electrode will be connected in parallel to carry the RF currents. It is also possible to use the individual sets of electrodes to "focus" energy along the length of the active zone even in the presence of saline, especially if the salt concentration is low. It should be appreciated that if dielectric tubes were provided to each electrode site then multiple spot ablation could be performed at selected sites. However, it is believed that the ability to generate a linear connected lesion will prove more effective at removing accessory pathways.

WHAT IS CLAIMED IS:

1. An electrophysiology device for treating tissue by energy delivered from an energy source, comprising:

an elongate catheter body 25 having a lumen for carrying fluid and having a distal end 31 and a proximal end 33, said catheter having a central axis 36;

at least one electrode site 18 located proximate said distal end 31;

a wire 37 for connection to said electrode site 18 and to said energy source 20;

at least one aperture 29 in said catheter body 25 being substantially perpendicular to said axis 36, and communicating with said central lumen 27;

a source 24 of electrolyte fluid 54 in communication with said central lumen 27;

whereby, energy from said energy source is directed by said wire 37 from said energy source to said electrode site 18, and energy is coupled to said electrolyte fluid 54 at said electrode site 18 and communicated to said tissue through said porous sheath 34.

2. The electrophysiology device of Claim 1 further including:

a porous sheath 34 covering said holes for permitting the exit of fluid from said lumen 25.

3. A method of treating tissue comprising the steps of:

positioning a porous surface adjacent said tissue;

directing electrolyte fluid into contact with said tissue, through said porous surface;

passing radio frequency current through said tissue by passing radio frequency current through said electrolyte fluid.

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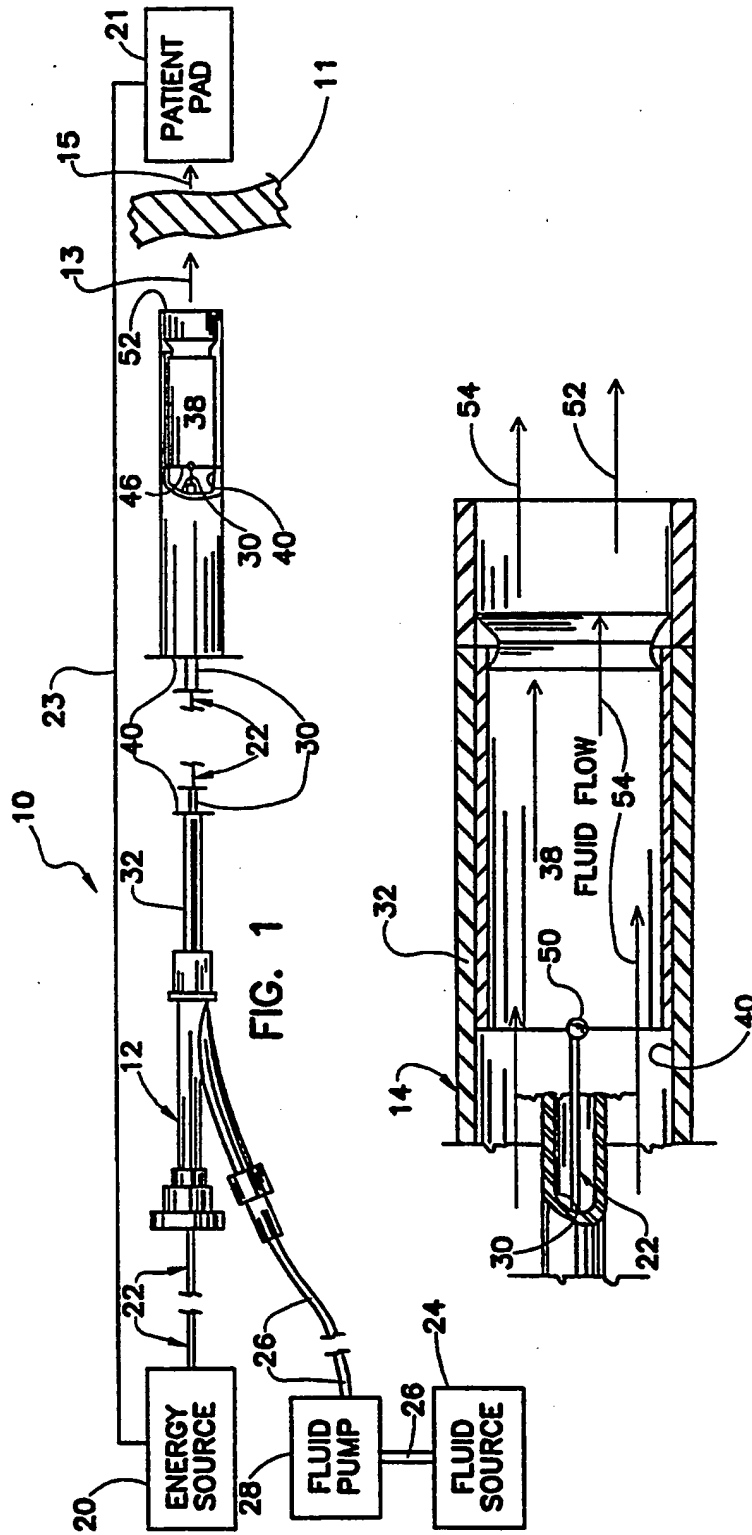


FIG. 2

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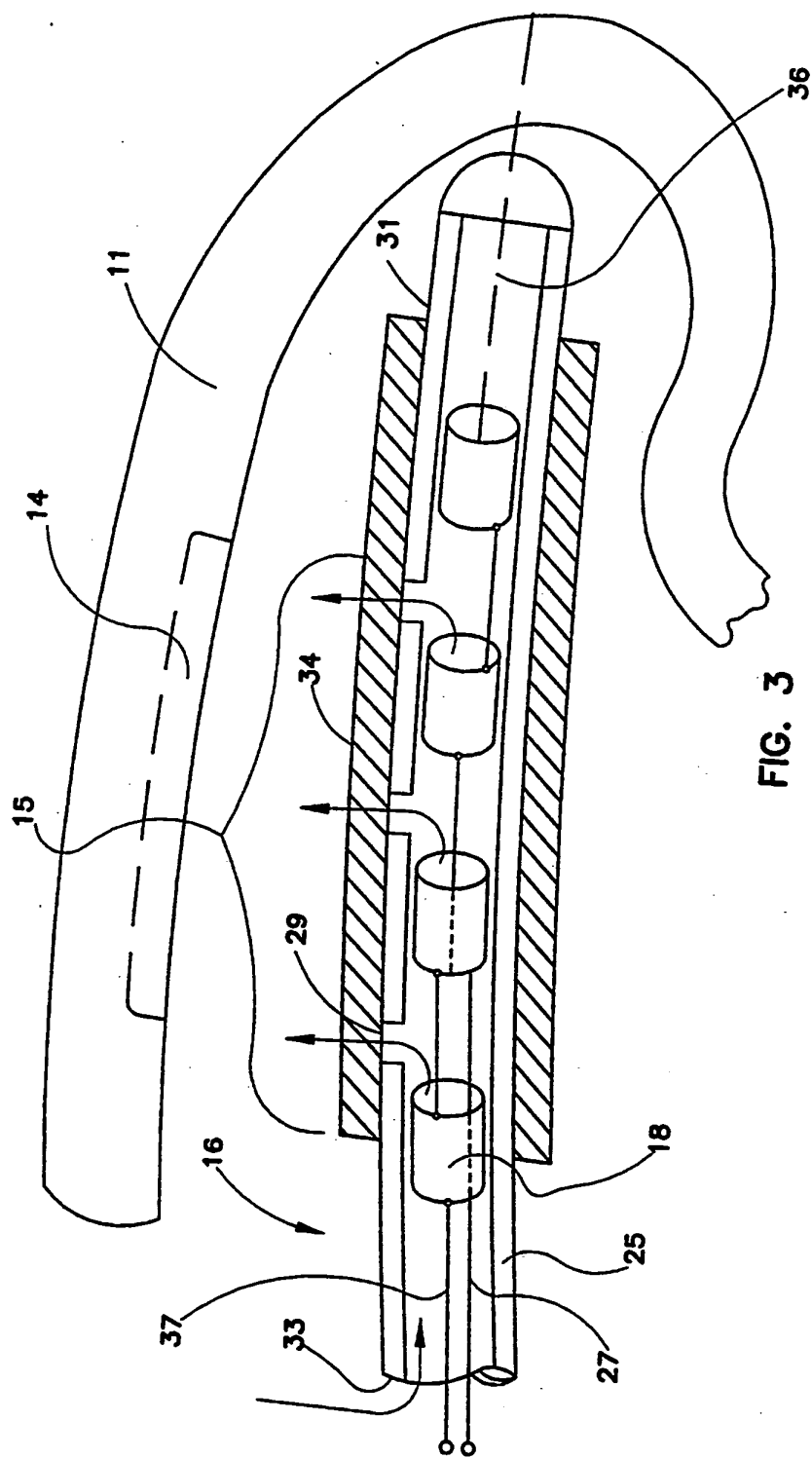


FIG. 3

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US 95/07576

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61N1/40

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61N A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US,A,4 801 459 (LIBURDY) 31 January 1989 see abstract; claim 1 ---	1,3
A	US,A,5 106 360 (ISHIWARA) 21 April 1992 see abstract ---	1,3
A	EP,A,0 253 677 (KUREHA) 20 January 1988 see column 3, line 14 - column 4, line 46 ---	1-3
A	WO,A,90 00419 (HENRY) 25 January 1990 see abstract -----	1,3

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Taccoen, J-F

INTERNATIONAL SEARCH REPORT

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Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A-4801459	31-01-89	US-A- 5190761	02-03-93
US-A-5106360	21-04-92	JP-A- 1085671	30-03-89
EP-A-0253677	20-01-88	JP-C- 1711081	11-11-92
		JP-B- 3080032	20-12-91
		JP-A- 63023676	30-01-88
		DE-D- 3787419	21-10-93
		DE-T- 3787419	10-03-94
		US-A- 5168880	08-12-92
WO-A-9000419	25-01-90	FR-A- 2634127	19-01-90